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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,873	03/08/2004	Jean-Pierre Hermet	1049-04	3189
35811 7590 01/15/2008 IP GROUP OF DLA PIPER US LLP ONE LIBERTY PLACE 1650 MARKET ST, SUITE 4900 PHILADELPHIA, PA 19103			EXAMINER HINES, JANA A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 10/795,873	<b>Applicant(s)</b> HERMET ET AL.	
	<b>Examiner</b> Ja-Na Hines	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 18-22 and 29-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-10, 13-17 and 23-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 16, 2007 has been entered.

### ***Amendment Entry***

2. The amendment filed October 16, 2007 has been entered. The examiner acknowledges the amendments to the specification. Claims 1, 4, and 23 have been amended. Claims 11-12, 18-22, 29-36 have been withdrawn. Claims 1-10, 13-17 and 23-28 are under consideration in this office action.

### ***Withdrawal of Objections***

3. The following objections and rejection have been withdrawn in view of applicants' amendments and arguments:

a) The objection of claims 4 and 23

### ***Response to Arguments***

4. Applicant's arguments filed October 16, 2007 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5, 8, 10, 14-17 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable Doshi et al., (US Patent 5,766,552) over in view of Schrenk et al., (US Patent 5,316,731).

The claims are drawn to a method for detecting contaminating microbes possibly present in a blood product comprising blood cells comprising: a) subjecting a sample of the blood product to an aggregation treatment of the blood cells, b) substantially eliminating aggregates formed in step (a) by passage of the sample over a first filter allowing passage of contaminating microbes, but not cell aggregates, c) selectively lysing residual cells of the filtrate obtained in step (b), d) adding a marker agent to label the contaminating microbes either during step (a) or step (b), e) recovering the contaminating microbes by passage of the lysate from step (c) over a second filter allowing passage of cellular debris, and f) analyzing material on the second filter to detect labeled contaminating microbes possibly retained by the second filter. The dependant claims are drawn to permeabilization agents, detergents, marker agents, blood products, antibodies, lectins, the filters and the device.

Doshi et al., teach that the separation of serum or plasma from whole blood is extremely important since it is difficult to conduct the analysis of dissolved blood components without interference from red blood cells (col. 1, lines 47-50). Red blood cells (RBC) are removed from whole blood samples by contacting a whole blood sample with an agglutinating agent (col. 7, lines 25-28). The agglutinating agents allow for the quick and efficient formation of clusters of RBC, be fast acting, have short reactivation time, are non-specific to blood types, and be stable and inexpensive (col. 5, lines 32-34). Doshi et al., teach antibodies as agglutinating agents since they are reactive and well known for agglutinating erythrocytes (col. 7-8, lines 66-6). These antibodies should recognize antigenic surface constituents such as glycoproteins (col. 8, lines 6-10). By contacting the RBC with agglutinating agent, the cells are agglutinated and trapped by the pad while the remainder of the fluid sample flows through readily (col. 6, lines 10-15). Doshi et al., teach the efficiency of filtration, along with the lysis of RBC wherein whole blood is passed through the filter and plasma is retained (col. 8, lines 54-56). Doshi et al., teach the removal of the RBC clusters by filtration (col. 11, lines 40-41). The preferred filtration uses a porous absorbent pad with mesh or pore size being from about 20 to about 500 microns (col. 62-65). This is within the instantly claimed size of pores for the first filter. The secondary filter has a very small pore size to permit plasma to pass, ideally a pore size between 1 and 5 microns (col. 12, lines 1-11). Doshi et al., teach having a reactant pad through which the fluid flows to allow for the production of a detectable signal (col. 14, lines 39-41). The analyte reacts with the reagents to produce a detectable signal

such as dyes, particles, and proteins with visible extinction coefficients (col. 14, lines 42-43). Thus, where the analyte is an enzyme substrate, the pad may be impregnated with the appropriate enzyme or enzymes to produce a product that is measured (col. 15, lines 10-13). The production of a detectable signal produced by enzymes teach the marker agent. The method teaches a measurement dye zone wherein the zone is coated or impregnated with an indicator material that reacts with the enzyme treated sample to give an indication of the presence or amount of analyte in the sample (col. 16, lines 23-27). Thus the indicator material that reacts with the enzyme treated sample material is the marker agent.

Doshi et al., teach one type of RBC agglutinating agent is lectins, including *Phaseolous vulgaris* (col. 7, lines 46-48). Other agglutinating agents include antibodies that have a binding affinity for a determinant present on the surface of red blood cells that recognizes antigenic surface constituents (col. 7-8, lines 65-8). Doshi et al, teach a minimum amount of antibody must be used in the blood separation device (col. 8, lines 43-45). Doshi et al., state that one skilled in the art will readily determine the optimum amount of antibody to be used in the method (col. 8, lines 49-51). Thus Doshi et al., teach using an appropriate concentration of antibody. The use of detergents where a lipophilic analyte is in the blood is disclosed (col. 15, lines 27-28). The detergents are anionic or cationic detergents (col. 15, lines 33). Thus the art teaches using cationic and anionic detergents. Doshi et al., teach using various sticking agents or adhesives (col. 15, lines 38-41). These sticking agents would meet the permeabilization

agents. However, Doshi et al., do not teach selectively lysing residual cells of the filtrate.

Schrenk et al., teach a selective reagent that lyses red and white blood cells but not microbial contaminants (col. 3, lines 16-18). Schrenk et al., teach the collection and processing of biological samples, such as blood and serum (col. 1, lines 5-7). Schrenk et al., teach a method useful for testing for microbial contamination (col. 3, lines 10-13). The art teaches using filters as a separation means (col. 2, lines 54-68). Schrenk et al., teach passage of the fluid through a filter where contaminating microorganisms are trapped on the membrane (col. 3, lines 35-43). Examples of useful reagents include saponin and ethylenediamine tetraacetate acid (EDTA) (col. 3, lines 22-23). Therefore, once the blood has been contacted with the reagent it is analogous to a concentrate and then may be subjected to testing for microbial contamination (col. 3, lines 47-50). The reaction time of the reagent is about 1 minute or more and will not causes lysis of the contaminating microorganisms (col. 4, lines 55-56). Schrenk et al., teach that an advantage is the ability to provide a concentrate of fluid which contains cellular debris and contaminating microbes without subjecting the blood sample to time consuming and expensive centrifugation techniques (col. 5-6, lines 65-3). Therefore the blood obtained from the procedure is subjected to testing for microbial contamination (col.3, lines 47-50).

Therefore, it would have been prima facie obvious at the time of applicants' invention to modify the method of Doshi et al., to include a lysis reagent and lysing step as taught by Schrenk et al., because Schrenk et al.,

teach that the lysis reaction reduces interference from RBC without lysing the contaminating microorganisms so as aid in their detection. No more than routine skill would have been necessary to include a lysis reagent and step in the method of detection, since the art teaches that it is desirable to rid a blood sample of substantially all blood cells since it is difficult to conduct an analysis of the blood components without interference from red blood cells when testing for microbial contamination. Moreover, there would have been a reasonable expectation of success in this modification since the art teaches that the lysis reagent and step does not harm the contaminants yet prepares the blood sample for microbial detection and analysis without time consuming and expensive techniques.

### ***Response to Arguments***

6. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been prima facie obvious at the time of applicants' invention to modify the method of Doshi et al., to include a lysis step as taught by Schrenk et al., because Schrenk et al., disclose the advantage



of providing a concentrate of fluid which contains cellular debris and contaminating microbes without subjecting the blood sample to time consuming and expensive centrifugation techniques (See Schrenk et al., col. 5-6, lines 65-3).

Applicants assert that Doshi discloses a process wherein blood is agglutinated at the same time that the red blood cells are separated/filtered from an absorbent pad that contains an agglutinating agent which is unlike the instant claims. The claims recite subjecting a sample of the blood product to an aggregation treatment of the blood cells, substantially eliminating aggregates formed in step (a) by passage of the sample over a first filter allowing passage of contaminating microbes, but not cell aggregates. During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." The Federal Circuit's en banc decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard. Therefore, Doshi et al., teach contacting a fluid sample containing RBC with a mixture of agglutinating agents, allowing the RBC to agglutinate and then trapping the aggregates while the remainder of the sample flow through (col. 6, lines 8-14). Therefore, Doshi et al., meet the limitations of the claims.

Applicants urge that there are also no teachings or suggestions in Doshi that would lead one skilled in the art to pluck the lysis aspect of Schrenk and insert it into the Doshi process. However, as previously stated, Doshi et al., disclose the difficulty in conducting the analysis of dissolved blood without

interference from red blood cells and the efficiency of lysing RBC while Schrenk et al., teach the benefits of a RBC lysis reagent that results in fluid which contains intact contaminating microbes, yet does not subject the blood to time consuming and expensive techniques, and decreases the amount of time necessary to prepare the blood for microbial detection. Therefore contrary to applicants' assertions, the Doshi et al., in view of Schrenk et al., provide motivation to lead of ordinary skill in the art to use the lysis reagent.

Applicants argue that the combined Doshi/ Schrenk method, which would recover lysed blood cells on the second filter and allow microorganisms to pass through the second filter which is in sharp contrast to the Applicants' claims. However, the filters of Doshi et al., recite the first filter being between 2 and 20 microns and the second filter being between 0.2 and 2 microns. Therefore, contrary to applicants' assertions, the same material will be trapped on both the first and second filters. There is no structural difference between the claimed filters and the prior art filters in order to patentably distinguish the claimed invention from the prior art. Therefore, the prior art filters are capable of performing the intended use eliminating aggregates and allowing passage of contaminating microbes in the first filter, and allowing the passage of cellular debris in the second filter.

Applicants' urge that their second filter recovers the contaminating microbes and allows the remaining materials, including cellular debris, to pass through the filter which is unlike the filter of Doshi et al. However, the claim recites recovering the contaminating microbes by passage of the lysate from step

(c) over a second filter allowing passage of cellular debris. Claim 26 states that the pores size of the second filter is between about 0.2 and 2 microns. Doshi et al., teach the secondary filter having a pore size that permits plasma to pass, a pore size between 1 and 5 microns with a mean pore size of 1.2 microns (col. 12, lines 1-12). Thus, Doshi et al., teach a secondary filter that meets the claimed limitations. There is no structural difference between the claimed secondary filter and the prior art secondary filter; therefore the instantly claimed filter is not patentably distinguishable from the secondary filter of Doshi et al. Therefore, if the prior art structure is capable of performing the use, then it meets the claims. The additional use of the secondary filter do not prevent Doshi from functioning in the same way as the claimed secondary filter.

Applicants' assert that Doshi fails to disclose analyzing the material on the second filter to detect labeled contaminating microbes possibly retained by the second filter. However, Doshi et al., teach having a reactant pad (filter) through which the fluid flows to allow for the production of a detectable signal (col. 14, lines 39-41). The analyte reacts with the reagents to produce a detectable signal (col. 14, lines 42-43). Therefore, where the analyte is an enzyme substrate, the pad (filter) may be impregnated with the appropriate enzymes to produce a detectable and measurable reaction (col. 15, lines 10-13). Contrary to applicants' assertion, Doshi et al., do teach the efficiency of analyzing the material on the second filter to detect labeled contaminating microbes possibly retained by the second filter.

Applicants' urge that Schrenk does not provide any teachings or suggestions to make such a combination and, in any event, there are no teachings or suggestions to make said combination. However, Doshi et al., provides the motivation for wanting the lysis of RBS step by stating the need for efficiency in the method detection. Schrenk et al., adds to that motivation by teaching a reagent which lyses red and white blood cells but not microbial contaminants. Therefore the detection of microbial contaminants is taught by both Doshi et al, and Schrenk et al. Therefore applicants' arguments are not persuasive and the rejection is maintained.

***Claim Rejections - 35 USC § 103***

7. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable Doshi et al., (US Patent 5,766,552) and Schrenk et al., (US Patent 5,316,731) further in view of Cathey et al., (US Patent 5,798,215).

The claims are drawn to a method for detecting contaminating microbes comprising a marker agent that comprises a fluorescent marker or an agent coupled to a flurochrome or an enzyme enabling degradation of substrate thereby made fluorescent wherein the fluorescence is detected by an excitation laser. The teachings of Doshi et al., and Schrenk et al., have been discussed above. However neither teaches a fluorescent marker or an agent coupled to a flurochrome or an enzyme enabling degradation of substrate thereby made fluorescent wherein the fluorescence is detected by an excitation laser.

Cathey et al., teach analyte detection assays wherein the assay platform comprises a filter (col. 6, lines 19-21). The separation means for separating sample components may be positioned in the flow path of the assay platform (col.6, lines 54-56). For example, a filter may be positioned such that in when samples comprise red blood cells, the red blood cells are retained while serum flows through the filter (col. 6, lines 56-60). Depending upon the nature of the sample, the sample may be subjected to prior treatment, such as filtration or cell separation (col. 12, lines 15-19). For blood, one may wish to remove red blood cells to provide plasma or serum (col. 12, lines 20-21). Upon substrate addition, the substrate flows into the main flow path, where it is converted by an enzyme to a detectable product (col. 14, lines 34-36). Fluorescent labels or enzymes are preferred because they convert substrates to non-diffusible dyes that are used in signal producing systems (col. 13, lines 60-64). These signal systems also provide for wider testing capabilities and are useful in microbial detection/diagnosis (col. 13, lines 64-66). Optical signals which may be detected and related to the presence and/or amount of analyte in the sample include emissions, e.g. from fluorescent labels or the fluorescence of a quenching member of a signal producing system (col. 14, lines 53-56). The optical signals are detected by a wide variety of means including devices that measure absorbance, transmissions, diffraction, resonance which includes lasers (col. 15, lines 13-34).

Therefore, it would have been prima facie obvious at the time of applicants' invention to modify the method of Doshi et al., and Schrenk et al., to

include a marker agent that comprises a fluorescent marker or an enzyme enabling degradation of substrate thereby made fluorescent wherein the fluorescence is detected by an excitation laser as taught by Cathey et al. because Cathey et al., teach that fluorescent labels convert substrates to non-diffusible dyes are used in signal producing systems. No more than routine skill would have been necessary to include a fluorescence marker in the method of detection, since the art teaches that it is desirable to use fluorescence detection signals to detect analytes and other microbes. Moreover, there would have been a reasonable expectation of success in this modification since only routine skill would have been required to use fluorescent agents coupled with an enzyme substrate when Doshi et al., already teach microbial detection with enzymatic substrates.

### ***Response to Arguments***

8. In response to applicant's argument that there is no suggestion to combine the references, due to the arguments drawn to Doshi et al., and Schrenk et al., However Doshi et al., and Schrenk et al., have been discussed above. In this case, it would have been prima facie obvious at the time of applicants' invention to modify the method of Doshi et al., and Schrenk et al., to include a fluorescent marker or an enzyme enabling degradation of substrate as taught by Cathey et al. because Cathey et al., teach that fluorescent labels convert substrates to non-diffusible dyes; are used in signal producing systems; since Doshi et al., already

teach the usefulness of markers agents in methods of detecting microbial contaminants.

Therefore applicants' arguments are not persuasive and the rejection is maintained.

***Claim Rejections - 35 USC § 103***

9. Claims 9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doshi et al., (US Patent 5,766,552) and Schrenk et al., (US Patent 5,316,731) further in view of Besson-Faure et al. (US Patent 6,168,925).

The claims are drawn to a method for detecting contaminating microbes comprising a specific antibody to a platelet antigen such as anti-GpIIb/IIIa.

Doshi et al., and Schrenk et al., have been discussed above however neither teaches a specific antibody to a platelet antigen such as anti-GpIIb/IIIa.

Besson-Faure et al., teach the anti-GpIIb/IIIa antibody as a specific antibody to a platelet antigen that causes aggregation. Besson-Faure et al., teach the analysis of platelet GpIIb/IIIa receptors (col. 1, lines 5-8). Activated platelets have this receptor which binds with very high affinity and causes aggregation of the platelets with each other (col. 1, lines 25-30). The activation of the platelets allows the receptor to bind with high affinity, which causes aggregation (col. 1, lines 27-31). The molecules also remain in circulation for long periods of time (col. 1, lines 57-60). Besson-Faure et al., teach anti-GpIIb/IIIa antibodies are publicly available (col. 3, lines 1-10). Thus, Therefore, it would have been prima facie obvious at the time of applicants' invention to

modify the method of Doshi et al., and Schrenk et al., to include the anti-GpIIb/IIIa antibody as a specific antibody to a platelet antigen as taught by Besson-Faure et al., because Besson-Faure et al., teach the a superior aggregation properties of anti-GpIIb/IIIa. No more than routine skill would have been necessary to include anti-GpIIb/IIIa in the method of detection, since the Doshi et al., that it is desirable to use antibody agglutinating agents that are quick, efficient at cluster formation, and fast acting and Besson-Faure et al., teach the anti-GpIIb/IIIa agglutinating agent which efficiently causes high affinity agglutination. Moreover, there would have been a reasonable expectation of success in this modification since only routine skill would have been required to use antibodies as agglutinating agents when Doshi et al., provides motivation for antibody agglutinating agents wherein the motivation is that antibodies are reactive, well known for agglutinating properties and recognize glycoproteins; and Besson-Faure et al., provide commercially available anti-GpIIb/IIIa agglutinating antibodies that cause high affinity agglutination.

### ***Response to Arguments***

10. In response to applicant's argument that there is no suggestion to combine the references, due to the arguments drawn to Doshi et al., and Schrenk et al., However Doshi et al., and Schrenk et al., have been discussed above. In this case, it would have been prima facie obvious at the time of applicants' invention to modify the method of detection as taught by Doshi et al., and Schrenk et al., which already teach antibody agglutinating agents and the need for antibodies



that are reactive, have agglutinating abilities and recognize glycoproteins; wherein the modification merely incorporates Besson-Faure et al., who provides commercially available anti-GpIIb/IIIa agglutinating antibodies.

Therefore applicants' arguments are not persuasive and the rejection is maintained.


### ***Conclusion***


11. No claims allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines   
January 7, 2008

  
MARK NAVARRO  
PRIMA: EXAMINER